REMARKS/ARGUMENTS

The claims are 1, 2 and 4-5. Claims 1 and 2 have been amended to better define the invention. Claim 3 has been canceled in favor of amended claim 2 and claim 4 has been amended to improve its form. In addition, new claim 5, similar to claim 4 but dependent on claim 2, has been added. Support for the claims may be found, *inter alia*, in the disclosure at page 4. Reconsideration is expressly requested.

Claim 3 was objected to as containing a typographical error. In response, claim 3 has been canceled and claim 2 has been amended which it is respectfully submitted overcomes the Examiner's objection on this basis.

Claims 1-4 were rejected under 35 U.S.C. 102(b) as being anticipated by *U.S. Patent No. 6,406,458 to Tilander*. Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by *U.S. Patent No. 5,090,963 to Gross et al*. Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by *U.S. Patent No. 5,571,261 to Sancoff et al*. Claim 4 was rejected under 35 U.S.C.

103(a) as being unpatentable over *Sancoff et al.* in view of *U.S. Patent No. 6,510,965 to DeCottignies et al.*

In response, Applicant has amended claim 1 to better define the invention and respectfully traverses the Examiner's rejections for the following reasons.

As set forth in claim 1 as amended, Applicant's invention provides an apparatus for the dosed dispensing of a fluid, especially an infusion fluid, including a housing with a fluid chamber and a pressure medium chamber by which a flexible wall of the fluid chamber can be pressurized by a gas pressure source including a carbonate formulation pressed into a tablet and an organic acid.

The housing consists of mutually detachably joined first and second housing parts. The first housing part forms the pressure medium chamber and the second housing part receives in an exchangeable manner the fluid chamber configured as a leak-proof

infusion bag. The first housing part forming the pressure medium chamber is sealed against the second housing part receiving the infusion bag by a membrane in a region of a separation plane of the first and second housing parts. The gas pressure source is replaceably connected with the pressure medium chamber by way of a plug-in coupling and at least one valve selected from the group consisting of a control valve and a pressure reduction valve.

In this way, Applicant's invention provides an apparatus for the dosed dispensing of a fluid that can be produced in a cost effective way, is mostly reusable and causes only very low operating costs.

None of the cited references discloses or suggests an apparatus for the dosed dispensing of a fluid in which the housing consists of two housing parts that are connected with one another, one of which forms a pressure medium chamber and the other of which replaceably accommodates a fluid chamber configured as a fluid-tight infusion bag, in which the housing part that forms the pressure medium chamber is sealed with regard

to the housing part that accommodates the infusion bag by means of a membrane provided in the region of the parting plane of the two housing parts, and in which the gas pressure source is replaceably connected to the pressure medium chamber by way of a plug-in coupling and a control valve and/or a pressure reduction valve.

Tilander discloses a device for metered dispensing of infusion fluids packaged in infusion bags. The *Tilander* device has an accommodation for the infusion bag that can be closed off with a lid and is provided in a housing. The infusion bag is laid into the device, and pressure can be applied to it, in controlled manner, when the lid is closed, by way of a pressure medium chamber to which a pressure medium is applied, in order to dispense the infusion solution. It is a particular disadvantage of these large and heavy devices that a patient is mobile only with restrictions, if at all, because of their size and weight, and that these devices, because of their complicated technology, cause not only high acquisition costs but also significant maintenance and installation costs. For this reason,

WO 95/23641 A1 discussed in the specification is believed to be the closest prior art. *WO 95/23641 A1* discloses a compact device with which the patients remain mobile and which can easily be carried along by the patients, for example in a pocket. The *WO 95/23641 A1* product has the disadvantage that it can be used only as a disposable product, that it is relatively expensive to produce, and that it must be disposed of, after use, with increased effort.

Against this background, Applicant's invention as set forth in claim 1 as amended is based on the task of creating as compact as possible a device for metered dispensing of infusion fluid, which device can be produced in cost-advantageous manner, can be reused, at least for the most part, and causes only low operating costs. In addition, the patient is not supposed to be restricted with regard to his or her mobility by the apparatus as set forth in claim 1 as amended.

As recited in claim 1 as amended, Applicant's apparatus accomplishes this task by having the housing consist of two

housing parts that are connected with one another, one of which forms the pressure medium chamber, and the other of which replaceably accommodates the fluid chamber, which is configured as a fluid-tight infusion bag, and by sealing the housing part that forms the pressure medium chamber, with regard to the housing part that accommodates the infusion bag, by means of a membrane provided in the region of the parting plane of the two housing parts, and by having the gas pressure source replaceably connected to the pressure medium chamber by way of a plug-in coupling and a control valve and/or pressure reduction valve.

Applicant's apparatus as recited in claim 1 as amended also specifies that the housing part that forms the pressure medium chamber is sealed, with regard to the housing part that accommodates the infusion bag, "by a membrane in the region of a separation plane of the first and second housing parts" as discussed at page 4, last full paragraph of Applicant's disclosure.

Even if no information concerning the size and the weight of

the devices is explicitly evident from *Tilander* relied on by the Examiner, it is respectfully submitted that an evaluation of the drawings that must be used for an interpretation of the disclosure makes evident that the device according to *Tilander* has a significant size that exceeds the size of the infusion bags. Furthermore, it is known from practice that these devices specifically cannot guarantee complete mobility of the patients.

For this purpose, Applicant's apparatus as recited in claim 1, as amended, forms the housing from only two housing parts, which are furthermore adapted to the infusion bag, in terms of their size, and therefore the size is essentially determined by the infusion bag size. This size is increased only by the replaceable gas pressure source that must additionally be provided. In this connection, the smallest possible construction height can be particularly guaranteed in that the housing consists of only two housing parts that are connected with one another, one of which forms the pressure medium chamber, and the other of which replaceably accommodates the fluid chamber configured as a fluid-tight infusion bag. Thus, it is guaranteed

that the fluid is completely driven out of the fluid-tight infusion bag in that the housing part that forms the pressure medium chamber is sealed, with regard to the housing part that accommodates the infusion bag, by means of the membrane provided in the region of the parting plane of the two housing parts.

The design of the apparatus as set forth in claim 1 as amended is not only simple and cost-advantageous in production, but also ensures that the infusion bag can be laid into the device in simple manner and that the infusion fluid can be completely driven out of the infusion bag. In this connection, the membrane rests against the housing wall of the housing part 6 when the full infusion bag is laid into the device, and is displaced in the direction of the housing wall of the housing part 7 as the infusion fluid is driven out. The membrane then lies against this housing wall, with the interposition of the infusion bag, and has driven the infusion fluid out completely. By providing the replaceable disposable gas pressure source, it is guaranteed that at least the major portion of the device can be reused, and only the gas pressure source and the infusion bag

must be replaced between two infusions that are to be administered. Specifically by the combination of these measures as set forth in claim 1 as amended, the result is achieved that a compact device for metered dispensing of fluid is created, with which a patient remains completely mobile during administration of an infusion.

Gross et al. and *Sancoff et al.*, which have been cited as anticipatory prior art with respect to claim 1, are further afield. *Gross et al.* discloses neither a housing that accommodates an infusion bag for administration of infusion fluid nor a replaceable gas pressure source. According to *Gross et al.*, a housing part, together with a membrane, is configured as an infusion bag, which has the result that a major portion of the device cannot be reused and that conventional infusion bags cannot be administered with the *Gross et al.* device.

Sancoff et al. discloses the state of the art discussed in detail in the introductory portion of Applicant's disclosure. *Sancoff et al.* is a disposable product that is not suitable for

administering infusion fluids packaged in infusion bags which Applicant's apparatus as set forth in claim 1 as amended is designed to avoid.

The remaining reference to *DeCottignies et al.*, which has been cited as a secondary reference with respect to claim 4, has been considered but is believed to be no more pertinent. *DeCottignies et al.* discloses a fluid dispenser and it is respectfully submitted contains no teaching that could be reasonably applied to the prior art cited by the Examiner, including *Sancoff et al.*, that would lead one skilled in the art to Applicant's apparatus as set forth in claim 1 as amended. The *DeCottignies et al.* device is a simple dispenser, particularly for soaps and the like, which accommodates a fluid bag in a housing and from which the fluid to be dispensed is removed with a manually activated suction pump. Therefore, it is respectfully submitted that *DeCottignies et al.* relates to a state of the art that differs from that to which Applicant's apparatus as set forth in claim 1 as amended is directed. In any event, it is respectfully submitted that there is no disclosure or suggestion

in *DeCottignies et al.* of an apparatus having the structure set forth in Applicant's claim 1 as amended or the benefits that are achieved by that structure.

Accordingly, it is respectfully submitted that claim 1 as amended, together with claims 2 and 4-5 which depend directly or indirectly thereon, are patentable over the cited references.

In summary, claims 1, 2 and 4 have been amended, claim 3 has been canceled and new claim 5 has been added. In view of the foregoing, it is respectfully requested that the claims be allowed and that this application be passed to issue.

Respectfully submitted,
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Amy Klein

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